Corrective Action Guidelines for Vaccine Storage and Handling Incidents

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Background and reason for protocol

Only viable vaccine protects children from vaccine preventable diseases. When vaccines are not stored and handled properly, they may no longer be viable. Health care providers receiving state supplied vaccine are responsible for assuring the viability of state supplied vaccine.

This Corrective Action Protocol supports local health jurisdiction (LHJ) staff and state staff decisions about corrective action when providers have preventable vaccine storage and handling incidents resulting in vaccine loss. The Protocol describes preventable and non-preventable vaccine incidents. Providers may have to pay for vaccines that are wasted, spoiled, expired or lost. In some cases, they may replace wasted, spoiled or expired doses. LHJs should consult the Office of Immunization and Child Profile about vaccine storage and handling incidents and corrective action. LHJs must consult the Office before suspending or disenrolling a provider from the program due to storage and handling incidents.

Preventable versus non-preventable vaccine storage and handling incidents

Vaccine storage and handling incidents resulting in non-viable or wasted vaccine are:

- Preventable (negligent) if the incident could have been prevented by the provider or
- Non-preventable if the incident was beyond the provider's control.

We define vaccine storage and handling incidents further based on whether the vaccine was mishandled or wasted. We describe vaccine incident categories and definitions in this document.

Provider financial restitution
Financial restitution means the provider pays for the cost of replacement vaccine that is non-viable, wasted or lost due to preventable vaccine storage and handling incidents. We consider preventable vaccine incidents as provider negligence. The current Centers for Disease Control and Prevention (CDC) contract price determines the per dose cost the provider must pay for each dose of non-viable wasted or lost vaccine.

Provider inventory replacement:
When a storage or handling incident requires the replacement of state supplied vaccine, the provider may replace the mishandled state supplied vaccine with privately purchased vaccine. The replacement option requires the permission of the LHJ after consulting with state staff. The LHJ should consider this option on a case-by-case basis after consulting with the State Vaccine Manager or his or her designee. The provider must first show that they have privately purchased stock available or document the private purchase of replacement stock. Once the provider shows they have private stock available, then they may replace the state supplied vaccine. Replacement vaccine must be the same type as the mishandled vaccine and be appropriate for children less than 19 years of age. The expiration date must be long enough to assure its timely use.

Vaccine loss definitions

Expired (non-viable):	Any vaccine with an expiration date that has passed is non-viable. These incidents may or may not be preventable.
Spoiled (non-viable):	Any vaccine exposed to temperatures outside the recommended range and identified as non-viable. These incidents may or may not be preventable.
Wasted (unusable):	When a provider cannot use vaccine because it spilled, the vial was broken or damaged, or for another reason. These incidents are generally not preventable.
Lost or missing:	Vaccine cannot be accounted for, located or is missing. These incidents may or may not be preventable.

Determining if a vaccine storage and handling incident is negligent or not
Non-preventable vaccine storage and handling incidents occur when vaccines are wasted, expired, or spoiled or lost due to events that are beyond the control of the provider. The provider is not negligent in his or her handling of state supplied vaccines if the incident is truly non-preventable.

Preventable vaccine storage and handling incidents occur when vaccines are wasted, spoiled, expired or lost due to events the provider can prevent. We may consider the provider negligent when these types of incidents occur.

> If a provider repeatedly has negligent incidents, resulting in preventable vaccine losses, he or she may have to pay for the value of the mishandled or wasted vaccine.

Providers receiving state supplied vaccine must have current written storage and handling policies and procedures in place and follow them. The required policies include:

- The designation of a vaccine coordinator and at least one back-up staff

- Policies and procedures for proper vaccine storage, handling, receiving and transport
- An emergency back-up plan for responding to power failures, equipment failures or emergencies
    - The plan must be reviewed and updated annually or when staff responsible for vaccine storage and handling changes
- Protocols for vaccine ordering
- Procedures for inventory management and control
- Procedures for managing a vaccine wastage incident

Providers must document vaccine incidents and always notify their LHJ when state supplied vaccine is wasted, spoiled, expired or lost.

> When determining if a vaccine incident is negligent, staff should consider if the provider has all required written procedures in place, typically follows them and has made every effort to train staff on the procedures.

Below are some examples of preventable and non-preventable vaccine incidents. Vaccine incidents may result in vaccine losses. These examples do not include every possible type of incident. LHJs and state staff will consider vaccine storage and handling incidents on a case-by-case basis. LHJs may consult with state staff when responding to these types of incidents. LHJs must consult with the State Vaccine Manager or his or her designee before suspending or disenrolling a provider from the program due to storage and handling incidents.

Non-preventable vaccine incidents resulting in vaccine waste, expiration, spoilage or loss

Examples of non-preventable vaccine expiration: When vaccine is unused and exceeds its expiration date due to reasons beyond the provider's control.

- Influenza vaccine not used during the influenza season.
- Open multi-dose vial vaccine the provider cannot use prior to the manufacturer's expiration date.
- Single dose vials that expire when the provider notified the LHJ 3 months before the expiration date

Definition of non-preventable vaccine spoilage: When **v**accine is exposed to temperatures outside the recommended range for reasons beyond the provider's control and spoils.

- An electronic temperature monitor alarm or alarm company does not contact the appropriate staff (or provider) when temperatures go out-of-range. This type of incident is only considered not preventable if the provider follows all temperature monitoring requirements and has written procedures for using the electronic monitoring system in place (see Alarmed Electronic Vaccine Temperature Monitoring Guidelines). http://www.doh.wa.gov/Portals/1/Documents/Pubs/348-214_AlarmedElectronicVaccineTempMonitoringGuidelines.pdf
- If a vaccine loss occurs when a provider uses their emergency back-up procedures and moves vaccine to an alternate storage site and the alternate site has a power failure.
- If a vaccine loss occurs because the provider cannot transfer vaccine to their back-up storage facility or cannot fully implement their emergency back-up plan due to extenuating

circumstances. We consider this type of incident not preventable if the provider has a current written emergency plan in place and staff is trained on the plan.

- If a vaccine loss occurs due to refrigerator or freezer equipment problems and the provider immediately arranges for the repair or replacement of the equipment involved. The provider must give the LHJ proof of repair or replacement.
- The shipper (UPS, FedEx) does not deliver the vaccine to the provider in a timely manner. If a vaccine shipment is delayed, it is not always spoiled. The provider should contact the LHJ and state staff. They will determine if the shipment is spoiled.
- The temperature indicators in the shipping box show temperatures have gone out of range while in transit. The provider should contact the LHJ and state staff. They will determine if the shipment is spoiled. This type of incident is only considered not preventable the provider **must notify the LHJ within 2 hours of the vaccine shipment.**

Non-preventable wasted vaccine – When a provider cannot use vaccine because of the following:

- Accidents such as spillage
- A vial or syringe is accidentally dropped or broken
- When the clinician draws up vaccine at the time of visit, but the parent refuses or the provider changes the orders and the clinician cannot administer it
- When the LHJ determines vaccine waste occurred due reasons beyond the provider's control.

> Providers who *routinely* pre-draw (pre-fill) syringes that go unused and become non-viable are negligent in this area. Pre-drawing vaccines for later use, even if kept within temperature requirements so the vaccine stays viable, is not acceptable. Routinely pre-drawing syringes is not a best practice and is against state and federal vaccine requirements. Pre-drawing is acceptable if done following CDC guidelines for mass immunization clinics.

Non-preventable lost or missing vaccine: When vaccine cannot be located or is missing.

- The shipper (UPS, FedEx) does not deliver the vaccine to the provider. **The provider must report these incidents to the LHJ immediately.**
- The provider cannot reconcile the inventory due to a counting error with doses administered, inventory on hand or doses received.
    - If these types of errors occur repeatedly, the provider should receive education about inventory management.
    - Repeated incidents may be negligent and possibly fraudulent. The provider may have to complete corrective action including payment for or replacement of lost doses of vaccine.

Preventable (negligent) vaccine incidents resulting in vaccine waste, expiration, spoilage or loss

Examples of preventable vaccine expiration: Vaccine that is past its expiration date (except influenza vaccine) because:

- The provider failed to rotate vaccine stock and administering longer dated stock before short dated stock.

- The provider did not notify their LHJ or DOH three months prior to expiration date. The LHJ could not transfer the vaccine to another clinic before it expired because of the lack of notification.
- The provider did not transfer vaccine as directed and the vaccine expired before it was used.

Providers must notify their local health jurisdiction if they have vaccine that will expire within 90 days (3 months). Failure to notify the LHJ will result in a finding of negligent vaccine loss, and may require that the provider pay for the value of the lost vaccine.

Preventable vaccine spoilage incidents: When **v**accine exceeds the limits of approved storage and handling procedures and is not viable. The list below describes incidents that may result in non-viable vaccine.

- Pre-drawing or pre-mixing vaccine and not administering it. This practice is not acceptable. Providers who routinely pre-draw vaccines that go unused and become non-viable are negligent in this area. Repeated incidents may result in the provider paying for or replacing pre-drawn vaccines that spoil.
- When providers or their staff do not follow accepted storage and handling guidelines, vaccine losses may occur. Examples include;
    - Failing to unpack and store vaccines appropriately and immediately upon arrival
    - Failing to rotate stock so shorter dated vaccine is used before longer dated vaccine
    - Leaving vaccine out of the refrigerator or freezer and exposing the vaccine to temperatures that are too warm
    - Freezing vaccine meant to be refrigerated
    - Refrigerating vaccine meant to be frozen
    - Leaving the refrigerator unplugged
    - Leaving the refrigerator door open or ajar, increasing the temperature in the unit and exposing the vaccine to temperatures that are too warm
    - Not maintaining recommended refrigerator and freezer temperatures and exposing vaccines to temperatures that are too warm or too cold
    - Not moving vaccines to a backup site when storage unit temperatures are out of range
    - Failure to use thermometers with current certifications of calibration in each vaccine refrigerator and freezer compartment
    - Repeatedly marking temperatures in the out of range section of the temperature monitoring log, and using vaccines exposed to out of range temperatures
    - Failure to use appropriate storage equipment

- The provider does not give written documentation of refrigerator or freezer equipment repair or replacement to the LHJ within 30 days of identification of the problem.

The provider must place vaccines in a storage unit that maintains appropriate temperatures or remove it from the facility while awaiting equipment repair or replacement. When the provider gives the LHJ or state proof of the equipment's replacement or repair and temperatures stabilized, they may replace the vaccine.

Providers must allow 3 – 5 days for refrigerator or freezer temperatures to stabilize prior to using a new or newly repaired unit. Failure to do so, resulting in a vaccine loss, is a negligent vaccine loss.

- If a storage unit is unplugged or breaker tripped and the provider has not taken precautions against it (e.g., "do not un-plug" stickers, outlet guards and others)
- Transporting or shipping vaccine without the proper packaging or without care to ensure cold chain maintenance (e.g., packing refrigerated vaccines without cold packs or temperature monitors)
- Not using proper procedures for using an electronic temperature monitoring system or alarm company as described in the DOH Alarmed Electronic Vaccine Temperature Monitoring Guidelines. http://www.doh.wa.gov/Portals/1/Documents/Pubs/348-214_AlarmedElectronicVaccineTempMonitoringGuidelines.pdf

Preventable vaccine waste: Wasted vaccine is vaccine the provider cannot use for various reasons such as:

- The provider discards vaccine prior to the expiration date (e.g., discarding vaccine in a multi-dose vial 30 days after the vial is first used).
- The LHJ or state staff determines the provider did not make every effort to follow required storage and handling procedures resulting in wasted vaccine.

Preventable lost or missing vaccine – When vaccine cannot be located or accounted for or is missing.

- The LHJ or state staff determines the provider did not make every effort to follow required storage and handling procedures resulting in lost or missing vaccine.
- The provider is repeatedly unable to reconcile the clinic's vaccine inventory with vaccine use.

Determining the appropriate correction action

The following key points are fundamental to corrective action for vaccine storage and handling incidents.

- LHJ and state staff must use professional judgment when determining the severity and nature of each vaccine incident.
- LHJ and state staff must gather all information and clearly document the incident.
- LHJ and state staff must think about the number and type of incidents a provider has had. The LHJ should review how the provider responded to past incidents and their willingness to correct previous issues. This review will help the LHJ determine what corrective action is the best fit for the incident.
- Corrective action should be progressive and fit the severity and nature of the incident.
- The LHJ should write a letter to the provider documenting each corrective action step. The letter should clearly identify the reasons for the corrective action, the required provider activity, and the possible consequences for repeat offenses.
- LHJ staff should consult their LHJ leadership prior to starting corrective action requiring the provider to pay for mishandled or wasted state supplied vaccine.
- LHJs can consult with the state staff about vaccine storage and handling incidents and corrective action. LHJs must consult the State Vaccine Manager or his or her designee before suspending or disenrolling a provider from the program.

Determining when financial restitution is required

Anytime a vaccine loss occurs, the LHJ should review the provider's overall performance with vaccine storage and handling. Providers who consistently comply with the requirements of the State Childhood Vaccine Program and Provider Agreement and maintain best practices in vaccine storage and handling are likely to have few vaccine losses. Providers must complete a vaccine incident report for each incident. LHJs must document each incident, and if negligence is involved, send written follow-up to the provider and the department. The letter should outline consequences should additional incidents happen. The corrective action letter is the documentation needed to support progressive corrective action.

In all cases, providers must review and update all written vaccine policies and protocols to assure the protocols reflect best practice standards for vaccine storage and handling. The provider must assure all staff has current training on the protocols.

The provider may have to pay for the cost of the vaccine if a single negligent vaccine storage and handling incident is severe enough to warrant it. The LHJ should document the incident and proceed with the appropriate corrective action. If a provider has three negligent incidents of the same type within a year, the provider should pay for the cost of the vaccine for the third incident. LHJs and state staff should use progressive corrective action if a provider has multiple unrelated or different types of negligent vaccine incidents. It may include requiring the provider to pay for the lost vaccine.

The provider must pay the State Childhood Vaccine Program for the vaccine needed to revaccinate patients if a negligent vaccine storage and handling incident results in patients needing revaccination. The provider may also have to reimburse the State for vaccine to replace all stock lost due to the incident. The same is true for requirements to revaccinate due to improper vaccine administration. LHJs must consult the State Vaccine Manager or his or her designee before requiring payment for both revaccination stock and stock lost due to the incident.

Every incident of vaccine loss requires follow-up with the provider by the LHJ. The follow-up ensures the provider corrected the events leading to the loss. The LHJ must document all incidents and follow-up actions and report them to DOH.

Procedures for provider financial restitution

The LHJ will notify the provider in writing of the value of the vaccine they must replace because of negligent spoilage, expiration or waste. The LHJ will clearly describe the severity of the incident and reason for financial restitution. The notice should reference past incidents showing a pattern, and the progression of the corrective action. The notification will include the total doses of vaccine by type and the CDC cost of each vaccine. The provider should pay for the lost vaccine within 30 days of being notified unless they make other arrangements for payment.

Checks should be payable to the Washington State Department of Health and sent to:

Washington State Department of Health
Office of Immunization and Child Profile
Attn: Vaccine Manager
P.O. Box 47843
Olympia, WA 98504